

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: COLUMBIA UNIVERSITY
PATENT LITIGATION**

MDL NO. 1592

**IMMUNEX CORPORATION, a
Washington Corporation and
AMGEN INC., a Delaware Corporation,**

CIVIL ACTION NO.: 04-10740-MLW

C. D. Cal. No. CV 03-4349 MRP (CWx)

Plaintiffs,

Judge Mark L. Wolf

VS.

**THE TRUSTEES OF COLUMBIA
UNIVERSITY in the City of New York, a
New York Corporation,**

Defendant.

AND RELATED COUNTERCLAIM.

**MEMORANDUM OF PLAINTIFFS AMGEN INC. AND IMMUNEX CORPORATION
IN SUPPORT OF MOTION TO AMEND COMPLAINT**

Amgen Inc. and Immunex Corporation (collectively “Amgen”) request leave of the Court to amend the Complaint to add newly discovered information. Since the filing of the pending Second Amended Complaint, additional events have occurred and additional facts have surfaced from discovery and investigation in this action, which newly discovered information is closely related to the facts and claims for relief already pleaded by Amgen. Courts freely grant leave to amend complaints absent a showing of undue prejudice, particularly where the amendments are

based upon newly discovered information. Accordingly, amendment is proper here and Amgen respectfully requests that the Court grant Amgen's motion for leave.

STATEMENT OF THE FACTS

Amgen filed its Second Amended Complaint ("SAC") in December, 2003. At that time, it sought several items of relief that the Court has held are mooted by Columbia's recently-expanded Covenant not to Sue, and also several additional items of relief:

- Amgen's request for a declaration that additional royalties are not due under the parties' license agreement, entirely apart from the issue of the validity or enforceability of the '275 patent (First Claim for Relief); and
- Amgen's request for a declaration that Columbia's misconduct in connection with the events leading to the '275 patent constitutes "repressive practices" in breach of the license agreement from Columbia to Amgen (Seventh Claim for Relief).¹

Since that time, several additional relevant events have occurred and facts come to light, closely tied to the transactions and occurrences alleged in the Second Amended Complaint. To avoid unnecessary multiplication of litigation, Amgen seeks to amend to reflect those changes, which principally relate to:

- Certain revelations, during recent Court-ordered discovery of witnesses to preserve testimony and through related investigation, showing that Columbia

¹ The license agreement between Columbia and Amgen – like some or all of the other Columbia licenses – incorporate by reference the obligations Columbia was required to assume to the United States in order to obtain an assignment of the technology in question. One of those obligations is to refrain from "repressive practices." See SAC, Exhibit E, at § 2(b) and Appx. A thereto, conditions (j) and (l). Accordingly, Columbia's misconduct leading to the '275 patent and other Axel patents is relevant to the ongoing issue of Columbia's performance under the license agreement. Columbia does not dispute that there are ongoing disputes between the parties in this action regarding their performance and duties under that agreement.

committed misconduct in procuring the original Axel patents, thus providing additional evidence in support of Amgen's claims.²

- The revelation on September 22, 2004, that Columbia granted at least one other licensee, Genetics Institute, a more favorable royalty rate, entitling Amgen to relief under the "most favored nation" royalty provision of its license at issue in this action, and discovery of overpayments by Immunex Corporation to Columbia under its license at issue in this action;³
- Columbia's purported termination of its license agreement with Amgen on March 9, 2004, reaffirmed September 13 in response to this Court's Order;⁴
- A continued pattern of misconduct by Columbia – including its application to reissue the '275 patent – that forms further evidence of its "repressive practices," which are relevant to Columbia's performance under its license agreement with Amgen.⁵

In some cases, these additional facts had not yet occurred when the current complaint was filed, including Columbia's purported termination of the Amgen license agreement and Columbia's filing of a reissue application to broaden the '275 patent.

² This matter is already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* Fifth Defense), but in light of additional discovery should also be added to the Complaint. The new material is found in paragraphs 30-44 of the proposed Third Amended Complaint ("TAC") filed herewith as Exhibit A. A redline of the TAC against the SAC is attached as Exhibit B. The facts alleged in section E(ii) through (vii) of the TAC are reordered but are found, respectively, in sections E(v), (vi) and (i) through (iv) of the SAC.

³ These matters are already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* denials of paragraphs 14-16, 18-20, and Sixteenth Defense), but in light of additional discovery should also be added to the Complaint for affirmative relief (*see* TAC, ¶¶ 78-80).

⁴ *See* paragraph 74-75 of the TAC.

⁵ This matter is already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* Twelfth Defense), but in light of additional discovery should also be added to the Complaint (*see* TAC, ¶ 75).

The other proposed amendments result from facts that have only recently come to light. Amgen learned of the fact that Columbia had granted more favorable royalty terms to Genetics Institute (but not given Amgen the benefit of those more favorable terms) when Genetics Institute filed its license in this action on September 22, 2004, as Exhibit 15 to the Declaration of Patricia Carson in opposition to Columbia's Emergency Motion to Dismiss. Additional facts regarding Columbia's misconduct in prosecution of the prior expired Axel patents – failure to disclose material prior art – also came to light recently. For example, following up on information first received in September, 2004, the Court's Orders for preservation of testimony allowed Amgen to establish at the deposition of prior art witness Dr. Goodgal on October 18 and 19, 2004 the facts, *inter alia*, that (1) at least by February 25, 1980, Dr. Goodgal carried out cotransformation of CHO cells with the gene for ouabain resistance and the gene conferring the ability to survive in the absence of the amino acid proline, and (2) in October 1979, Dr. Goodgal discussed with Michael Wigler his work on CHO cell transformation using the ouabain resistance gene. *See* TAC, ¶¶ 34-36, 38-39.⁶

None of the proposed amendments would circumvent the Court's ruling on Columbia's Emergency Motion to Dismiss. On the contrary, all of the proposed amendments relate to issues that are still pending in this Court despite the ruling on Columbia's motion to dismiss, and none is directed to challenging the continued enforcement of the '275 patent. As Columbia agrees and proclaims, its counterclaims – asserting that it performed all contractual conditions on its part to be performed and that Amgen owes additional royalties – are still at issue in this case.

⁶ Similarly, the Court's orders for preservation of testimony allowed Amgen to determine at the deposition of Dr. Srinivasan on September 14, 2004 and the deposition of Dr. Siminovitch on November 16, 2004, *inter alia*, that (1) while Dr. Srinivasan was on sabbatical from Columbia University from September 1977 to September 1978, he and Dr. William H. Lewis worked in Dr. Siminovitch's laboratory, and successfully transformed CHO cells; and (2) Dr. Srinivasan informed Richard Axel in a July 1978 letter about this work on CHO cell transformation using several markers including a mutant dhfr gene. *See* TAC, ¶¶ 32-33, 40. Investigation of

Additionally, Amgen's request for a declaration that no royalties are owed survives (First Claim for Relief), as does its claim that Columbia has not complied with its contractual obligations because its conduct (including that leading to the '275 patent) breached its contractual obligations to Amgen to refrain from "repressive practices" (Seventh Claim for Relief).⁷ Each of the proposed amendments is directly relevant to these remaining issues in the case: Columbia's additional misconduct, e.g., in procuring the prior expired Axel patents, is further evidence of Columbia's repressive practices (Seventh Claim for Relief, and also a defense to Columbia's Counterclaims), and also provides an inequitable conduct defense to Columbia's ongoing claims for additional royalty (like that pleaded now in the Third Claim for Relief with regard to the '275 patent). Columbia's failure to inform Amgen of the more favorable royalty rate to Genetics Institute, and facts showing overpayment by Immunex, are directly relevant to Amgen's claim that no further royalty is owed and indeed support affirmative contractual recovery of the overpayments. Columbia's purported termination of the license agreement based on non-payment of contested amounts was wrongful and should be declared ineffective.

ARGUMENT

I. LEAVE TO AMEND SHOULD BE GRANTED IN THIS ACTION.

A. Leave To Amend Is Liberally Granted, Especially In Cases Which Have Barely Progressed Beyond The Pleading Stage and Where the Amendments are Based Upon Newly Discovered Information.

these matters led Amgen to discover additional misconduct of Columbia in failure to disclose prior art in the prosecution of the prior expired Axel patents. *See* TAC , ¶¶ 42-43.

⁷ The transferor Court rejected Columbia's argument that Amgen's claim based on contractual "repressive practices" was duplicative of Amgen's claims under the patent laws based on overlapping facts. That Court explained that plaintiffs "claim that by engaging in the acts of which the Plaintiffs complain Columbia violated the repressive practices provision in the license agreements, in addition to and apart from any violation of the patent laws that those same acts may have constituted." Memo. of Decision, denying Columbia's Motion to Dismiss, Jan. 27, 2004, at 11.

Although amendment of pleadings is largely a matter within the discretion of the district court, Rule 15(a) provides that “leave shall be freely given when justice so requires.”

Farkas v. Texas Instruments, Inc., 429 F.2d 849, 851 (1st Cir. 1970), *cert. denied*, 401 U.S. 974, 91 S.Ct. 1193, 28 L.Ed.2d 324 (1971). *See also One Beacon Insurance Co. v. Electrolux*, 223 F.R.D. 21, 24 (D. Mass. 2004) (“Leave to amend under Rule 15 ‘is freely given when justice so requires’ absent an adequate basis to deny amendment such as futility, bad faith, undue delay or a dilatory motive”).

This is especially true where, as here, the case is still in the pretrial stage:

[D]elay itself will not serve as a basis for denying . . . [the] motion unless the defendant is prejudiced Moreover, such prejudice ordinarily is not considered to have occurred unless the motion is made during or after the actual trial Since the defendants have completed only initial discovery, they should be able to prepare their defense to these new claims.

New Balance Athletic Shoe, Inc. v. Puma USA, Inc., 118 F.R.D. 17, 20-21 (D. Mass. 1987) (internal citations and quotations omitted). *See also English v. General Electric Co.*, 765 F. Supp. 293, 297 (E.D.N.C. 1991), *aff’d*, 977 F.2d 572 (4th Cir. 1992) (plaintiff allowed to amend complaint to add factual allegations because “[a]lthough original complaint was filed more than four years ago, the action is still in discovery and no useful purpose would be served by denying leave to amend the factual allegations of the complaint”).

The Supreme Court has recognized several factors when determining whether justice requires a district court to grant leave to amend. Those factors include: undue delay, bad faith or dilatory motive on the part of the movant; repeated failure to cure deficiencies by amendments previously allowed; undue prejudice to the opposing party by virtue of allowance of the amendment; and futility of the amendment. *See Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962) (“Of course, the grant or denial of an opportunity to amend is within the discretion of the District Court, but outright refusal to grant the leave without any justifying

reason appearing for the denial is not an exercise of discretion; it is merely abuse of that discretion and inconsistent with the spirit of the Federal Rules”). Indeed, even where discovery is complete, “[a]mendments should be granted unless the court finds an inordinate measure of undue delay, dilatory motive, futility, or undue prejudice.” *Martin v. Sands*, 62 F. Supp. 2d 196, 198 (D. Mass. 1999) (permitting defendants to amend answer despite completion of discovery and delay of seventeen months between filing of answer and the motion to amend).

As explained below, at this early stage in the litigation, Amgen’s proposed amendments are properly brought to the attention of the Court without undue delay, without dilatory motive and would not be futile or unduly prejudice Columbia.

Amgen’s motion was brought without undue delay and without dilatory motive: as explained above, the proposed amendments are based upon new events and newly-discovered information. As reflected in Federal Rule of Civil Procedure 15(d) (allowing supplementation of complaints to include later-occurring events), leave is particularly appropriate as to occurrences or events that have happened since the date of the pleading to be supplemented.

A motion to supplement the pleadings under Rule 15(d) is addressed to [the] sound discretion of the Court, and should be granted when doing so will promote the justiciable disposition of the case, will not cause undue prejudice or delay or trial inconvenience and will not prejudice the rights of any parties to the action. *Bates v. Western Electric*, 420 F. Supp. 521, 525 (E.D. Pa. 1976). Liberality is the rule in permitting supplemental pleadings. *Weisbord v. Michigan State University*, 495 F. Supp. 1347, 1350 (W.D. Mich. 1980).

Structural Systems, Inc. v. Sulfaro, 692 F. Supp. 34, 36 (D. Mass. 1988). *Accord Boston Police Superior Officers Federation v. Jordan*, 1984 U.S. Dist. LEXIS 19036, *2 (D. Mass. 1984) (“Supplemental pleadings should be freely granted where it will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action.

Rowe v. U.S. Fidelity & Guar. Co., 421 F.2d 937 (4th Cir. 1970)”). Leave to amend is also appropriate as to newly-discovered information. *Cf. Kas v. Financial General Bankshares, Inc.*, 105 F.R.D. 453 (D.D.C. 1985) (granting motion to amend complaint to include new facts discovered as a result of the completion of discovery and finding no undue delay, bad faith or dilatory motive where the “new facts were not known earlier by the plaintiffs and thus could not have been included in the complaint or first amended complaint; and that as soon as these facts came to light, plaintiffs promptly sought to bring these facts to the attention of the Court by filing the instant motion”). *Accord, Strawhecker v. Laurel School District*, 100 F.R.D. 7 (W.D. Pa. 1983) (granting motion to amend complaint where amendments would enhance judicial economy and where valid reason for delay in filing motion for leave to amend existed where facts were unknown at time that original complaint was filed and were subsequently discovered through discovery process).

Amgen’s amendments similarly are not futile.

“Futility” means that the complaint, as amended, would fail to state a claim upon which relief could be granted. In reviewing for “futility,” the district court applies the same standard of legal sufficiency as applies to a Rule 12(b)(6) motion.

Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996). Amgen’s amendments do not fail to state a claim upon which relief may be granted. Amgen merely seeks to add additional facts to its already pending First Claim, which Columbia has not attacked as failing to state a claim. Amgen also merely seeks to add additional facts to already pending Seventh Claim, which Columbia unsuccessfully sought to dismiss. Amgen seeks to amend its previous Third Claim which, though mooted as to the ‘275 patent by this Court’s November 5 Order, should be directed at the prior issued Axel patents to add recently discovered inequitable claims, which are pled with particularity and are not vulnerable to a motion to dismiss for failure to state a claim.

Finally, the proposed amendments would not unduly prejudice Columbia. The amendments are sought before any significant amount of discovery has been taken. And, contrary to Columbia's arguments in the Joint Report, the amendments are not being introduced after Amgen's action has been dismissed. The amendments are to add facts pertinent to issues that do not depend on further enforcement of the '275 patent and therefore that have not been dismissed. Columbia's argument against a proposed supplementation of Biogen's complaint – that a court should not grant leave to amend after a case has been resolved – is very different from the situation where, as here, there is no final judgment on the merits and outstanding claims admittedly remain before the Court. *See Stewart v. Angelone*, 186 F.R.D. 342, 343 (E.D. Va. 1999) (granting habeas petitioner's motion to amend where motion was filed five months before "the time this Court would address its merits" and distinguishing *Briddle v. Scott*, 63 F.3d 364 (5th Cir. 1995), cited by Columbia against Biogen's proposed supplementation, because there the district court had "'rendered judgment on the merits dismissing the petition for writ,' and the petitioner had then waited another thirteen months after [the] ruling before seeking a third amendment.'"). Where only part of a case is dismissed on a motion, there is no dispositive ruling to weigh against amendment of a complaint. *See Bush v. United Parcel Service*, 2000 WL 1780353 (N.D. Ill. 2000) (granting defendant's motion to file a third amended complaint despite the court's dismissal of claims for failure to state a claim); *In re One Meridian Plaza Fire Litigation*, 1993 WL 308726 (E.D. Pa. 1993) (granting motion for leave to file second amended complaint despite order granting in part and denying in part defendant's motion to dismiss).

B. Additionally, The Very Strong Policy In Favor Of Punishing Misconduct In The Prosecution Of Patents Supports The Addition Of Recently-Uncovered Facts Pertaining To Such Misconduct.

In this case the policy of liberal amendment is reinforced by the policy favoring punishing Columbia's misconduct at the PTO. In *In re Recombinant DNA Technology Patent and Contract Litigation*, 850 F. Supp. 769 (S.D. Ind. 1994), the court granted a motion to amend to assert a patent misuse defense, explaining:

[W]e are mindful that other courts have found leniency of particular importance when considering whether to allow a party to amend the pleadings to raise the issues of patent misuse and consequent unenforceability since "the possession and assertion of patent rights are issues of great importance to the public."

Id. at 772 (quoting from *Key Pharmaceuticals, Inc. v. Lower*, 373 F. Supp. 1190, 1193 (S.D.N.Y. 1974)).

In *Key Pharmaceuticals, Inc.*, plaintiff-licensee sued defendant-licensor seeking rescission of the original agreement due to fraud in its inducement and violations of the Sherman Act. After discovery, the plaintiff-licensee moved to amend its complaint in order to add additional facts concerning the antitrust allegations and to delete the fraud claims. The defendant-licensor opposed, arguing that the amendment would radically alter the legal theory and factual basis of the case and would require extensive additional discovery. However, the court granted the motion to amend, recognizing the general principle that leave to amend should be freely given (*Id.* at 1193) and further stating that a court

should be particularly lenient in allowing amendment of the pleadings to raise issues of patent misuse and consequent unenforceability since "the possession and assertion of patent rights are 'issues of great moment to the public'." *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815, 89 L. Ed. 1381, 65 S. Ct. 993 (1945), quoting from *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246, 88 L. Ed. 1250, 64 S. Ct. 997 (1944). The implementation of this public policy is not "at the mercy of the parties," but the Court should, even *sua sponte*, refuse to enforce patents which have been misused by attempting to extend the patent monopoly. *Vitamin Technologists v. Wisconsin Alumni Research Foundation*, 146 F.2d 941, 944-945 (9th Cir. 1944).

Id. at 1193-94. Thus, Amgen's motion to amend is especially proper to present recently-uncovered facts relating to Columbia's misconduct in prosecution leading to all of the Axel patents.

II. LEAVE TO AMEND IS ALSO APPROPRIATE BECAUSE THE ALTERNATIVE WOULD LEAD TO JUDICIAL INEFFICIENCY

Allowing Amgen's amendments to reflect new information not only would serve the usual interests of expeditiously reaching the merits of controversies and avoiding piecemeal litigation, but would also present a clearer record on which to judge the commonality of the pleadings remaining following the Court's November 5, 2004 Order.⁸ If pleading amendment were deferred until after the Court considers the commonality of issues remaining in these MDL proceedings and Columbia's request for remand, then either this Court or another court will likely need later to re-evaluate the commonality of the issues in the remaining cases in light of these additional events and facts.

At Columbia's request, the JPML ordered these cases transferred to this Court because of the overlap of facts and issues. The Panel decided that placing these cases in one court would "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a); *see also In re Library Editions of Children's Books*, 399 F. Supp. 1139, 1141 (J.P.M.L. 1969) ("The objective of the legislation is to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions.") The just and efficient conduct of the actions mandates that Amgen be afforded the opportunity to amend its complaint before any decision whether to remand parts of these actions to transferor courts. It is appropriate to consider not only the current pleadings but proposed pleadings as well

⁸ For example, Biogen Idec has also pleaded, in its new action, a wrongful termination of its license, on the grounds that Columbia engaged in "efforts to enforce and extend the life of an invalid and unenforceable patent"

when considering remand of MDL cases. In *In re South Central States Bakery Products Antitrust Litigation*, 462 F. Supp. 388 (J.P.M.L. 1978), the defendants in a case involving six consolidated antitrust actions moved to remand one of the actions based on the proposed dismissal of the other consolidated actions. The JPML denied the motion for remand, in part because the plaintiffs in some of the other consolidated actions had indicated that they might file additional actions which would necessitate further multidistrict proceedings.⁹ *Id.* at 391 n.4. It would be most appropriate to update the pleadings before, not after, briefing on what if anything should be suggested for remand.

CONCLUSION

For the above reasons, Amgen requests that the Court grant Amgen's Motion to Amend the Complaint.

Dated: December 8, 2004

Respectfully submitted,

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and that Columbia engaged in "repressive licensing practices." See *Biogen Idec Inc. v. Trustees of Columbia University*, Case No. 04-12009 MLW, Complaint, at ¶¶ 70-75. These same points are at issue in Amgen's action.

⁹ The JPML also noted that it was not certain that the other consolidated cases would in fact be dismissed. *Id.* at 391.